PRESS RELEASE

DEBIOPHARM TAKES A STEP FORWARD FOR CHILDREN WITH CPP: ENROLLMENT COMPLETION FOR THE PHASE III TRIAL EVALUATING THE FIRST EVER YEARLY INJECTABLE TRIPTORELIN FORMULATION

LIBELULA™ trial completed enrollment of Central Precocious Puberty (CPP) patients in North and South America, advancing the path for Debio 4326, a triptorelin injectable 12-month extended-release formulation

Lausanne, Switzerland – November 6, 2025 – Debiopharm (www.debiopharm.com), a privately-owned, Swiss-based biopharmaceutical company aiming to develop innovative therapies and to improve patient quality of life, today announced the successful completion of patient enrollment in its open-label, single-arm, multi-center Phase III study (NCT06129539) 'A Study to Assess the Efficacy, Safety and Pharmacokinetics of Debio 4326 in Pediatric Participants Receiving Gonadotropin-Releasing Hormone Agonist Therapy for Central Precocious Puberty (LIBELULA™)'. The completion of enrollment is a significant milestone for the development of **Debio 4326**, a unique injectable, biodegradable **12-month extended-release formulation** of the established treatment, triptorelin.

The LIBELULA™ trial is being conducted across the **United States, Argentina, Brazil, Chile, and Mexico**, leveraging Debiopharm's proprietary **DEBIO SPHERE™** Long-Acting Release Platform technology and expertise in developing extended-release formulations to potentially reduce the frequency of injections for children with Central Precocious Puberty (CPP) from current injectable options (1-, 3-, or 6-month) to **once a year**.

"We acknowledge that frequent injections can be burdensome for both children and their families. Advancing extended-release formulations to market is essential for enhancing patient quality of life. The completion of enrollment in this CPP trial marks important progress toward our commitment to improved patient care, while also demonstrating Debiopharm's capabilities in innovative drug delivery solutions addressing unmet medical needs," stated **Cédric Sager, Chief Executive Officer at Debiopharm Research & Manufacturing**.

"Reaching full enrollment for the LIBELULA™ trial brings us closer to a significant advancement for children burdened by Central Precocious Puberty. While existing treatments are very effective, the promise of a reliable, once-a-year injectable formulation like Debio 4326 simplifies the treatment schedule to reduce the logistical and emotional stress on families and children." **Karen Klein, M.D.,** *Clinical Investigator, Interim Chief of Endocrinology/Diabetes Division at Rady Children's Hospital – San Diego and Clinical Professor of Pediatrics at UC San Diego School of Medicine*

The LIBELULA™ trial aims to assess the efficacy, safety, and pharmacokinetics of Debio 4326. Debiopharm looks forward to sharing the study's results in due course.

About Central Precocious Puberty

Central precocious puberty (CPP) occurs at an unusually early age, before 8 years of age in girls and before 9 years of age in boys [1-2]. It is characterized by premature development of secondary sexual characteristics (e.g. breasts for girls and enlarged testicles for boys), accelerated growth and bone maturation leading to reduced adult height. CPP is triggered by an increase in the release of the gonadotropin-releasing hormone in the brain and premature activation of the hypothalamic-pituitary-gonadal axis. This early activation can be due to specific genetic alterations, central nervous system lesions, and social stressors but frequently has no identified etiology [3]. The approximative prevalence of CPP is 1 in 5,000-10,000 among Caucasians, more frequent in girls than in boys globally [4]. Precocious puberty may be associated with psychosocial difficulties and carries potential negative implications for long-term health including increased risk of metabolic complications, such as type 2 diabetes, weight gain, obesity, cardiovascular disease, as well as depression, and even premature death [5-10]. Early puberty has also been associated with an increased risk of breast cancer in women. In men, it may increase the risk of prostate cancer [11-13]. Since the early 1980s, Gonadotropin-Releasing Hormone agonists (GnRHa) such as triptorelin have been the standard of care for the treatment of CPP [14-16]. Treatment aims to preserve adult height and prevent social and psychological difficulties and the various potential consequences on long-term health. Currently, there are several different extended-release GnRHa formulations ranging from monthly injections to subcutaneous implants for annual use [17]. While the latter may have a longer duration of action, it requires yearly surgical positioning.

About Debio 4326

Debio 4326 is a unique injectable, biodegradable 12-month extended-release formulation of triptorelin designed to further reduce the frequency of injections and burden of administrations, particularly considering its intended use in a pediatric population. Based on favorable efficacy and safety data with the different triptorelin 1-, 3- and 6-month formulations, Debio 4326 aims to preserve efficacy while providing increased comfort, ensure long-term compliance, and reduce stress for children and their parents. Debio 4326 is manufactured by Debiopharm Research & Manufacturing in Martigny Switzerland.

Debiopharm is engaged in partnering activities for the future registration and commercialization of Debio 4326 in the United States.

Debiopharm's commitment to patients

Debiopharm aims to develop innovative therapies that target high unmet medical needs primarily in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then hand stewardship to large pharmaceutical commercialization partners to maximize patient access globally.

For more information, please visit www.debiopharm.com
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Sources

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